

## **IN THE CLAIMS**

Please amend the claims as follows, canceling original claims 29 - 31:

Claim 1. (original): A method of optimizing the power required by a mechanical cardiac pumping device in steady-state operating condition, said method comprising the steps of:

- a. modeling the physical system, or at least a portion thereof, of the patient who will receive the mechanical cardiac pumping device;
- b. identifying an operating condition of the native heart of the patient who will receive the mechanical cardiac pumping device to which the mechanical cardiac pumping device will respond;
- c. using the model of the physical system from step a, above, to determine the required blood volume to be ejected from the mechanical cardiac pumping device;
- d. providing an initial estimate of the instantaneous power as a function of time across at least one period of the heartbeat required to be provided to the mechanical cardiac pumping device in order to provide the required ejected blood volume;
- e. evaluating the resultant ejected blood volume with data obtained from the model of the physical system;
- f. updating the estimate of the power requirement;
- g. iteratively performing steps e and f, above, until the power required to obtain the required ejected blood volume by the combined operation of the native heart and the VAD is identified;
- h. determining possible solutions to the instantaneous power as a function of time that allows the mechanical cardiac pumping device to provide the required ejected blood volume;

- i. choosing the solution from step h, above, that best matches the physiological constraints of the patient and provides for optimal power usage by the mechanical cardiac pumping device; and
- j. iteratively performing steps b through i, above, until the mechanical cardiac pumping device is optimized to respond to each desired operating condition of the native heart.

Claim 2. (original): A method of optimizing the power and energy required by a mechanical cardiac pumping device in steady-state operating condition, said method comprising the steps of:

- a. modeling the physical system, or at least a portion thereof, of the patient who will receive the mechanical cardiac pumping device;
- b. identifying an operating condition of the native heart of the patient who will receive the mechanical cardiac pumping device to which the mechanical cardiac pumping device will respond;
- c. using the model of the physical system from step a, above, to determine the required blood volume to be ejected from the mechanical cardiac pumping device;
- d. providing an initial estimate of the instantaneous power as a function of time across at least one period of the heartbeat required to be provided to the mechanical cardiac pumping device in order to provide the required ejected blood volume;
- e. evaluating the resultant ejected blood volume with data obtained from the model of the physical system;
- f. updating the estimate of the power requirement;

g. iteratively performing steps e and f, above, until the power required to obtain the required ejected blood volume by the combined operation of the native heart and the VAD is identified;

h. determining the possible solutions to the instantaneous power as a function of time, and the total energy over the pumping cycle that allows the mechanical cardiac pumping device to provide the required ejected blood volume;

i. choosing the solution from step h, above, that best matches the physiological constraints of the patient and provides for optimal power and energy usage by the mechanical cardiac pumping device; and

j. iteratively performing steps b through i, above, until the mechanical cardiac pumping device is optimized to respond to each desired operating condition of the native heart.

Claim 3. (original): A method of optimizing the energy required by a mechanical cardiac pumping device in steady-state operating condition, said method comprising the steps of:

a. modeling the physical system, or at least a portion thereof, of the patient who will receive the mechanical cardiac pumping device;

b. identifying an operating condition of the native heart of the patient who will receive the mechanical cardiac pumping device to which the mechanical cardiac pumping device will respond;

c. using the model of the physical system from step a, above, to determine the required blood volume to be ejected from the mechanical cardiac pumping device;

- d. providing an initial estimate of the instantaneous power as a function of time across at least one period of the heartbeat required to be provided to the mechanical cardiac pumping device in order to provide the required ejected blood volume;
- e. evaluating the resultant ejected blood volume with data obtained from the model of the physical system;
- f. updating the estimate of the power requirement;
- g. iteratively performing steps e and f, above, until the power required to obtain the required ejected blood volume by the combined operation of the native heart and the VAD is identified;
- h. determining possible solutions to the total energy over the pumping cycle that allows the mechanical cardiac pumping device to provide the required ejected blood volume;
- i. choosing the solution from step h, above, that best matches the physiological constraints of the patient and provides for optimal energy usage by the mechanical cardiac pumping device; and
- j. iteratively performing steps b through i, above, until the mechanical cardiac pumping device is optimized to respond to each desired operating condition of the native heart.

Claim 4. (original): A method of optimizing the power required by a mechanical cardiac pumping device in steady-state operating condition, said method comprising the steps of:

- a. modeling the physical system, or at least a portion thereof, of the patient who will receive the mechanical cardiac pumping device;

- b. providing an initial estimate of the instantaneous power as a function of time across at least one period of the heartbeat required to be provided to the mechanical cardiac pumping device in order to provide the required ejected blood volume;
- c. evaluating the resultant ejected blood volume;
- d. updating the estimate of the power requirement;
- e. iteratively performing steps c and d, above, until the power required to obtain the required ejected blood volume by the combined operation of the native heart and the VAD is identified;
- f. determining the possible solutions to the instantaneous power as a function of time that allows the mechanical cardiac pumping device to provide the required ejected blood volume;
- g. choosing the solution from step f, above, that best matches the physiological constraints of the patient and provides for optimal power usage by the mechanical cardiac pumping device; and
- h. iteratively performing steps b through g, above, until the mechanical cardiac pumping device is optimized to respond to each desired operating condition of the native heart.

Claim 5. (original): A method of optimizing the energy required by a mechanical cardiac pumping device in steady-state operating condition, said method comprising the steps of:

- a. modeling the physical system, or at least a portion thereof, of the patient who will receive the mechanical cardiac pumping device;

- b. providing an initial estimate of the instantaneous power as a function of time across at least one period of the heartbeat required to be provided to the mechanical cardiac pumping device in order to provide the required ejected blood volume;
- c. evaluating the resultant ejected blood volume;
- d. updating the estimate of the power requirement;
- e. iteratively performing steps c and d, above, until the power required to obtain the required ejected blood volume by the combined operation of the native heart and the VAD is identified;
- f. determining the possible solutions to the total energy over the pumping cycle that allows the mechanical cardiac pumping device to provide the required ejected blood volume;
- g. choosing the solution from step f, above, that best matches the physiological constraints of the patient and provides for optimal energy usage by the mechanical cardiac pumping device; and
- h. iteratively performing steps b through g, above, until the mechanical cardiac pumping device is optimized to respond to each desired operating condition of the native heart.

Claim 6. (original): A method of optimizing the power and energy required by a mechanical cardiac pumping device in steady-state operating condition, said method comprising the steps of:

- a. modeling the physical system, or at least a portion thereof, of the patient who will receive the mechanical cardiac pumping device;

- b. providing an initial estimate of the instantaneous power as a function of time across at least one period of the heartbeat required to be provided to the mechanical cardiac pumping device in order to provide the required ejected blood volume;
- c. evaluating the resultant ejected blood volume;
- d. updating the estimate of the power requirement;
- e. iteratively performing steps c and d, above, until the power required to obtain the required ejected blood volume by the combined operation of the native heart and the VAD is identified;
- f. determining the possible solutions to the instantaneous power as a function of time and total energy over the pumping cycle that allows the mechanical cardiac pumping device to provide the required ejected blood volume;
- g. choosing the solution from step f, above, that best matches the physiological constraints of the patient and provides for optimal power and energy usage by the mechanical cardiac pumping device; and
- h. iteratively performing steps b through g, above, until the mechanical cardiac pumping device is optimized to respond to each desired operating condition of the native heart.

Claim 7. (original): The method of any one of claims 1 through 6, wherein the modeled physical system is used to determine the required blood volume to be ejected from the mechanical cardiac pumping device by discretizing the modeled physical system with Finite Element Methods and Computational Fluid Dynamics into mass, damping, and stiffness matrices, and their corresponding elemental displacements.

Claim 8. (original): The method of any one of claims 1 through 6, wherein the physical system is modeled with MRI data and the modeled physical system is used to determine the required ejected blood volume from the mechanical cardiac pumping device by evaluating the MRI data.

Claim 9. (original): The method of any one of claims 1 through 6, wherein at least some components of the physical system are modeled utilizing a lumped-parameter model.

Claim 10. (original): The method of any one of claims 1 through 6, wherein at least some components of the physical system are modeled utilizing a distributed-parameter model.

Claim 11. (original): The method of any one of claims 1 through 6, wherein at least some components of the physical system are modeled utilizing a continuum model.

Claim 12. (original): The method of any one of claims 1 through 6, wherein neural networks are utilized to determine the instantaneous power as a function of time, and the total energy over the pumping cycle, that allows the cardiac device to provide the required ejected blood volume.

Claim 13. (original): The method of any one of claims 1 through 6, wherein heuristic methods are utilized to determine the instantaneous power as a function of time, and the



total energy over the pumping cycle, that allows the cardiac device to provide the required ejected blood volume.

Claim 14. (original): The method of any one of claims 1 through 6, wherein the operating condition of the native heart to which the mechanical cardiac pumping device will respond is heart rate.

Claim 15. (original): The method of any one of claims 1 through 6, wherein the operating condition of the native heart to which the mechanical cardiac pumping device will respond is ventricular volume.

Claim 16. (original): The method of any one of claims 1 through 6, wherein the operating condition of the native heart to which the mechanical cardiac pumping device will respond is ventricular pressure.

Claim 17. (original): The method of any one of claims 1 through 6, wherein the operating condition of the native heart to which the mechanical cardiac pumping device will respond is at least a portion of the ECG signal.

Claim 18. (original): The method of any one of claims 1 through 6, wherein the mechanical cardiac pumping device is a left ventricular-assist device and the operating conditions of the native heart to which the device will respond are at least one of: heart rate,

heart phase, left ventricular volume, right ventricular volume, left ventricular pressure, and right ventricular pressure.

Claim 19. (original): The method of any one of claims 1 through 6, wherein the mechanical cardiac pumping device is a left ventricular-assist device and the operating conditions of the native heart to which the device will respond are at least one of: heart rate as a function of time, heart phase, left ventricular volume as a function of time, right ventricular volume as a function of time, left ventricular pressure as a function of time, and right ventricular pressure as a function of time.

Claim 20. (original): The method of any one of claims 1 through 6, wherein the mechanical cardiac pumping device is a right ventricular-assist device and the operating conditions of the native heart to which the device will respond are at least one of: heart rate, heart phase, left ventricular volume, right ventricular volume, left ventricular pressure, and right ventricular pressure.

Claim 21. (original): The method of any one of claims 1 through 6, wherein the mechanical cardiac pumping device is a right ventricular-assist device and the operating conditions of the native heart to which the device will respond are at least one of: heart rate as a function of time, heart phase, left ventricular volume as a function of time, right ventricular volume as a function of time, left ventricular pressure as a function of time, and right ventricular pressure as a function of time.

Claim 22. (original): The method of any one of claims 1 through 6, wherein the mechanical cardiac pumping device is a bi-ventricular-assist device and the operating conditions of the native heart to which the device will respond are at least one of: heart rate, heart phase, left ventricular volume, right ventricular volume, left ventricular pressure, and right ventricular pressure.

Claim 23. (original): The method any one of claims 1 through 6, wherein the mechanical cardiac pumping device is a bi-ventricular-assist device and the operating conditions of the native heart to which the device will respond are at least one of: heart rate as a function of time, heart phase, left ventricular volume as a function of time, right ventricular volume as a function of time, left ventricular pressure as a function of time, and right ventricular pressure as a function of time.

Claim 24. (original): The method of any one of claims 1 through 6, wherein the mechanical cardiac pumping device is a total artificial heart.

Claim 25. (original): A method of optimizing the control scheme of a controller for a mechanical cardiac pumping device, said method comprising the steps of:

- a. simulating the steady-state physical condition of a patient who will receive the mechanical cardiac pumping device;
- b. identifying a new, target steady-state condition;
- c. determining which outputs of the physical system to monitor to best perform the transition from one steady-state to another;

d. determining the best combination of inputs, outputs, and modifications that achieve transient transfer from one steady-state to another without destabilizing the dynamic system; and

e. storing the information determined in steps c and d, above, in the controller.

Claim 26. (original): A method of assisting the cardiac function of the native heart of a patient using an implanted ventricular-assist device, said method comprising the steps of:

a. monitoring with a controller a steady-state condition of the physical system of the patient having the implanted ventricular-assist device;

b. directing with the controller the optimal power required to sustain the steady-state while meeting physiological constraints;

c. determining with the controller when the physical system of the patient has left the steady-state operating condition;

d. determining with a controller a new, target steady-state condition;

e. while the physical system of the is not in a steady-state operating condition, iteratively performing the following steps i-v:

i. monitoring inputs from the physical system of the patient, the inputs being at least one of: a measure of the heart phase,  $X/X_{max}$ , and the shape of  $X/X_{max}$ ;

ii. evaluating with the controller the desired outputs from the combined native heart and ventricular-assist device required at a new steady-state condition, the outputs being at least one of: heart rate, blood volume ejected by

the native heart, blood volume ejected by the ventricular-assist device, and the ECG trace;

iii. monitoring with a controller the actual outputs of the physical dynamic system, the outputs being at least one of: heart rate, blood volume ejected by the native heart, blood volume ejected by the ventricular-assist device, and at least a portion of the ECG trace;

iv. modifying with a controller the actual output data according to feedback transfer matrices stored within the controller;

v. transmitting with the controller modified inputs from step iv, above, such that the desired outputs from step ii, above, are achieved without destabilizing the dynamic system of the patient during the transient period between steady-states;

f. iteratively performing the steps a-e, above, so long as the ventricular-assist device is in operation.

Claim 27. (original): A method of assisting the cardiac function of the native heart of a patient using an implanted total artificial heart device, said method comprising the steps of:

a. monitoring with a controller a steady-state condition of the physical system of the patient having the implanted total artificial heart device;

b. directing with the controller the minimum power required to sustain the steady-state while meeting physiological constraints;

c. determining with the controller when the physical system of the patient has left the steady-state operating condition;

- d. determining with a controller a new, target steady-state condition;
- e. while the physical system of the is not in a steady-state operating condition, iteratively performing the following steps i-v:
  - i. monitoring inputs from the physical system of the patient, the inputs being at least one of: a measure of the heart phase,  $X/X_{max}$ , and the shape of  $X/X_{max}$ ;
  - ii. evaluating with the controller the desired outputs from the combined native heart and ventricular-assist device required at a new steady-state condition, the outputs being at least one of: blood volume ejected by the total artificial heart, and at least a portion of the ECG trace;
  - iii. monitoring with a controller the actual outputs of the physical dynamic system, the outputs being at least one of: blood volume ejected by the total artificial heart, and at least a portion of the ECG trace;
  - iv. modifying with a controller the actual output data according to feedback transfer matrices stored within the controller;
  - v. transmitting with the controller modified inputs from step iv, above, such that the desired outputs from step ii, above, are achieved without destabilizing the dynamic system of the patient during the transient period between steady-states;
- f. iteratively performing the steps a-e, above, so long as the total artificial heart device is in operation.

Claim 28. (original): A method of assisting the cardiac function of the native heart of a patient using an implanted ventricular-assist device, said method comprising the steps of:

- a. allowing the native heart to pump as much blood as it is able prior to activation of the ventricular-assist device;
- b. activating the ventricular-assist device to provide additional pumping action as the blood-ejection phase of the native heart nears completion such that the native heart pumps more blood than it would unaided due to the reduction of back pressure in the native ventricle caused by the pumping action of the ventricular-assist device;
- c. coordinating the timing of the action and length of the pumping stroke of the ventricular-assist device with the ejected blood volume and rhythm of the native heart such that the power required by the ventricular-assist device is the optimal needed to pump the required volume of blood while meeting physiological constraints;
- d. varying the stroke displacement over time and resulting power over time of the ventricular-assist device such that the power required by the ventricular-assist device is the optimal needed to pump the required volume of blood while meeting physiological constraints;
- e. iteratively performing steps a through d, above, so long as the ventricular-assist device is in operation.

Claims 29 - 31 (cancelled).

Claim 32. (original): A device to assist the function of a cardiac ventricle, the device comprising:

- a. a first magnet having an open center and formed of high ferromagnetic-constant material;
- b. a first vessel surrounding the first magnet and defining a space in fluid communication with the blood flow output great vessel of the diseased ventricle of the patient using the device, the first magnet being movable within the first vessel in substantially fluid-tight relation thereto;
- c. a second magnet formed of high ferromagnetic-constant material and in magnetic communication with the first magnet so that the respective magnetic fluxes of the first magnet and the second magnet affect each other, so that the first magnet and the second magnet are biased toward and tend to lock to one another, to thereby move in the same direction as one another;
- d. a second vessel encasing the second magnet and defining a space, the second magnet being movable within the space in substantially fluid-tight relation to the second vessel, the space defined by the second vessel being in fluid communication with a hydraulic pump for actuating the second magnet; and
- e. an one-way valve connected to the first magnet, the one-way valve being movable with the first magnet, and adapted to cause movement of blood from the diseased ventricle to and into the great vessel associated with that diseased ventricle.



Claim 33. (original): The device of claim 32, wherein the device is a L-VAD and is sized and shaped for positioning between the aortic valve and the aortic arch of the patient using the device.

Claim 34. (original): The device of claim 32, wherein the device is a R-VAD and is sized and shaped for positioning between the pulmonary valve and the bifurcation of the pulmonary trunk of the patient using the device.

Claim 35. (original): A device (58, 74) to assist the function of a cardiac ventricle, the device comprising:

- a. a first annular magnet (54) formed of high ferromagnetic-constant material;
- b. a first sleeve (68) surrounding the first annular magnet (54) and defining a space in fluid communication with the blood flow output great vessel of the patient using the device, the first annular magnet (54) being longitudinally and reciprocally slideable within the first sleeve in substantially fluid-tight relation thereto;
- c. a second annular magnet (44) formed of high ferromagnetic-constant material and sized and shaped for placement exterior of the first sleeve (68), the second annular magnet (44) being disposed coaxially in relation to and in magnetic communication with the first annular magnet (54), so that the respective magnetic fluxes of the first magnet and the second magnet affect each other, so that the first annular magnet and the second annular magnet are biased toward and tend to lock to one another, and to thereby move in the same direction as one another;

d. a second sleeve (72) encasing the second annular magnet (44), the second annular magnet being longitudinally and reciprocally slideable between the first sleeve (68) and the second sleeve in substantially fluid-tight relation to the first sleeve and the second sleeve, and the second sleeve (72) defining an annular space (86) radially outwardly of the first sleeve (68) for longitudinal travel therein of the second annular magnet (44), the annular space (86) being in fluid communication with a hydraulic pump for actuating the second annular magnet (44); and

e. an one-way valve (70) connected to the first annular magnet (54) and disposed transversely in relation to the longitudinal axis of the first annular magnet (54), the one-way valve being movable with the first magnet, and closed when moving away from the origin of the valve annulus when the device is in normal use position, to thereby cause blood of the patient to move out of a diseased ventricle and toward the great vessels associated with that diseased ventricle as the first annular magnet (54) moves in a direction toward the great vessels of the diseased ventricle due to magnetic flux of the second annular magnet, the one-way valve further being adapted to be open when moving in a direction away from the great vessels of the diseased ventricle, to thereby permit blood of the patient to flow through the one-way valve into the space defined by the first sleeve (68) when the second annular magnet moves away from the great vessels of the diseased ventricle.

Claim 36. (original): The device of claim 35, wherein the entire device (58, 74) is of sufficiently small size and weight for placement in normal operative position between the valve

annulus and at least a portion of the great vessels of the diseased ventricle of a patient using the device, to assist or replace the function of at least a portion of the diseased native heart.

Claim 37. (original): The device of claim 35, wherein the device is a L-VAD and is sized and shaped for positioning between the aortic valve and the aortic arch of the patient using the device.

Claim 38. (original): The device of claim 35, wherein the device is a R-VAD and is sized and shaped for positioning between the pulmonary valve and the bifurcation of the pulmonary trunk of the patient using the device.

Claim 39. (original): A system for assisting cardiac ventricular function, the system comprising a hydraulic pumping assembly and a cardiac ventricular assist device in fluid communication with the hydraulic pumping assembly, wherein the ventricular assist device comprises:

a. a first magnet having an open center and formed of high ferromagnetic-constant material;

b. a first vessel surrounding the first magnet and defining a space in fluid communication with the blood flow output great vessel of the diseased ventricle of the patient using the device, the first magnet being movable within the first vessel in substantially fluid-tight relation thereto;

c. a second magnet formed of high ferromagnetic-constant material and being in magnetic communication with the first magnet, so that the respective magnetic

fluxes of the first magnet and the second magnet affect each other, so that the first magnet and the second magnet are biased toward and tend to lock to one another, to thereby move in the same direction as one another;

d. a second vessel encasing the second magnet and defining a space, the second magnet being movable within the space in substantially fluid-tight relation to the second vessel, the space defined by the second vessel being in fluid communication with a hydraulic pump for actuating the second magnet; and

e. an one-way valve connected to the first magnet, the one-way valve being movable with the first magnet, and adapted to cause movement of blood from the diseased ventricle to and into the great vessel associated with that diseased ventricle.

Claim 40. (original): The system of claim 39, wherein the ventricular assist device is a L-VAD and is sized and shaped for positioning between the aortic valve and the aortic arch of the patient using the device.

Claim 41. (original): The device of claim 39, wherein the ventricular assist device is a R-VAD and is sized and shaped for positioning between the pulmonary valve and the bifurcation of the pulmonary trunk of the patient using the device.

Claim 42. (original): A system for assisting cardiac ventricular function, the system comprising a hydraulic pumping assembly and a cardiac ventricular assist device in fluid communication with the cardiac ventricular assist device, wherein the ventricular assist device comprises:

- a. a first annular magnet (54) formed of high ferromagnetic-constant material;
- b. a first sleeve (68) surrounding the first annular magnet (54) and defining a space in fluid communication with the blood flow output great vessel of the diseased ventricle of the patient using the device, the first annular magnet (54) being longitudinally and reciprocally slideable within the first sleeve in substantially fluid-tight relation thereto;
- c. a second annular magnet (44) formed of high ferromagnetic-constant material and sized and shaped for placement exterior of the first sleeve (68), the second annular magnet (44) being disposed coaxially in relation to and in magnetic communication with the first annular magnet (54), so that the respective magnetic fluxes of the first magnet and the second magnet affect each other, so that the first annular magnet and the second annular magnet are biased toward and tend to lock to one another, and to thereby move in the same direction as one another;
- d. a second sleeve (72) encasing the second annular magnet (44), the second annular magnet being longitudinally and reciprocally slideable between the first sleeve (68) and the second sleeve in substantially fluid-tight relation to the first sleeve and the second sleeve, and the second sleeve (72) defining an annular space (86) radially outwardly of the first sleeve (68) for longitudinal travel therein of the second annular magnet (44), the annular space (86) being in fluid communication with a hydraulic pump for actuating the second annular magnet (44); and
- e. an one-way valve (70) connected to the first annular magnet (54) and disposed transversely in relation to the longitudinal axis of the first annular magnet (54),

the one-way valve being movable with the first magnet, and closed when moving away from the origin of the valve annulus when the device is in normal use position, to thereby cause blood of the patient to move out of a diseased ventricle and toward the great vessels associated with that diseased ventricle as the first annular magnet (54) moves in a direction toward the great vessels of the diseased ventricle due to magnetic flux of the second annular magnet, the one-way valve further being adapted to be open when moving in a direction away from the great vessels of the diseased ventricle, to thereby permit blood of the patient to flow through the one-way valve into the space defined by the first sleeve (68) when the second annular magnet moves away from the great vessels of the diseased ventricle.

Claim 43. (original): The system of claim 42, wherein the entire device (58, 74) is of sufficiently small size and weight for placement in normal operative position between the valve annulus and the great vessels of the diseased ventricle of a patient using the device, to assist or replace the function of at least a portion of the diseased native heart.

Claim 44. (original): A system for assisting cardiac ventricular function, the system comprising a hydraulic pumping assembly and a cardiac ventricular assist device (VAD) in fluid communication with the hydraulic pumping assembly, wherein the hydraulic pumping assembly comprises:

- a. an encapsulated hydraulic pump having:
  - a pumping chamber for retaining hydraulic fluid therein, the pumping chamber having opposed first and second ends;

at least one electromagnetic coil surrounding the pumping chamber;  
a substantially solid high ferromagnetic-constant magnet disposed longitudinally, slideably and reciprocally within the pumping chamber to act as a piston for driving hydraulic fluid within the pumping chamber in response to signals from a battery/controller assembly;

b. a fluid line having a first end and a second end, the first end of the fluid line being connected to and in fluid communication with an the first end of the pumping chamber and the second end of the fluid line being connected to and in fluid communication with the second end of the pumping chamber, the VAD being in fluid communication with the fluid line at a point on the fluid line after the point of connection of the check valve and before the connection of the second end of the fluid line and the second end pump chamber; and

c. a battery/controller assembly operatively connected to the check valve and to the at least one electromagnetic coil to provide electric power and control signals to the pump, the battery controller assembly in electrical communication with the native heart of the patient using the system, to thereby receive signals corresponding to physiological parameters from the native heart.

Claim 45. (original): The system of claim 44, wherein the hydraulic pumping assembly further comprises a first end cap and a second end cap connected at opposed first and second ends of the pumping chamber, the first end cap and the second end cap each having an aperture in fluid communication with a hydraulic fluid line.

Claim 46. (original): The system of claim 45, and further comprising a check valve operatively connected in the fluid line between the connection of the first end of the fluid line and the second end of the fluid line to the first and second ends of the pumping chamber, respectively and the fluid line being in fluid communication with the VAD, after the point of connection of the check valve and before the connection of the second end of the fluid valve and the second end cap of the pump cylinder.

Claim 47. (original): The system of claim 45, wherein the information received from the native heart by the battery/controller assembly is at least a portion of an ECG signal from the patient.

Claim 48. (original): The system of claim 45, wherein the information received from the native heart by the battery/controller assembly is blood pressure information.

Claim 49. (original): The system of claim 45, wherein the information received from the native heart by the battery/controller assembly is blood volume information.

Claim 50. (original): The system of claim 45, wherein the at least one electromagnet coil is three electromagnetic coils disposed longitudinally and coaxially adjacent to one another along the length of the hydraulic pump.

Claim 51. (original): A system for assisting cardiac ventricular function, the system comprising a hydraulic pumping assembly and a cardiac ventricular assist device (VAD) in fluid



communication with the hydraulic pumping assembly, wherein the hydraulic pumping assembly comprises:

a. a hydraulic pump (42) having:

at least one electromagnetic coil (46, 48, 50) encapsulated so as to be fluid-tight, and defining a pumping chamber for retaining hydraulic fluid (52) therein, the pumping chamber having first and second opposed ends;

a first end cap (56) and a second end cap (57) connected at opposed first and second ends of the pumping chamber, respectively, the first end cap and the second end cap each having an aperture in fluid communication with a hydraulic fluid line,

a substantially solid high ferromagnetic-constant magnet (40) disposed longitudinally, slideably and reciprocally within the pumping chamber to act as a piston for driving hydraulic fluid within the pumping chamber in response to signals from a batter/controller assembly;

b. a fluid line (59, 60) having a first end and a second end, the first end of the fluid line being connected to and in fluid communication with an aperture in the first end cap and the second end of the fluid line being connected to and in fluid communication with an aperture in the second end cap, and the VAD being in fluid communication with the hydraulic pumping assembly at a point on the fluid line between the first end and the second end of the fluid line;

c. a check valve (84) operatively connected in the fluid line between the connection of the first end of the fluid line and the second end of the fluid line to the first and second end caps respectively, and the fluid line being in fluid communication with

the VAD, after the point of connection of the check valve and before the connection of the second end of the fluid valve and the second end cap of the pump cylinder;

d. a battery/controller assembly (65) operatively connected to the check valve and to the at least one electromagnetic coil to provide electric power and control signals to the pump, the battery controller assembly in electrical communication with the native heart of the patient using the system, to thereby receive electronic information, including at least portions of ECG signals, blood pressure signals and/or blood volume signals, from the native heart.

Claim 52. (original): The system of claim 51, wherein the battery controller assembly and the hydraulic pump are of sufficiently small size and weight to be entirely contained within the abdominal cavity of the patient using the system and the VAD is of sufficiently small size and weight to be entirely contained within the chest cavity of the patient using the system, and the complete system, including all wires and hydraulic fluid lines, is entirely contained within the body of the patient using the system, so that there is no part of the system extending exterior of the skin of a patient using the system when the system is in normal use position in the patient.

Claim 53. (original): A system for assisting cardiac ventricular function, the system comprising: a hydraulic pumping assembly and a cardiac ventricular assist device in fluid communication with the cardiac ventricular assist device, wherein the ventricular assist device comprises:

- a. a first annular magnet (54) formed of high ferromagnetic-constant material;
- b. a first sleeve (68) surrounding the first annular magnet (54) and defining a space in fluid communication with the blood flow output great vessel of a diseased ventricle of the patient using the device, the first annular magnet (54) being longitudinally and reciprocally slideable within the first sleeve in substantially fluid-tight relation thereto;
- c. a second annular magnet (44) formed of high ferromagnetic-constant material and sized and shaped for placement exterior of the first sleeve (68), the second annular magnet (44) being disposed coaxially in relation to and in magnetic communication with the first annular magnet (54), so that the respective magnetic fluxes of the first magnet and the second magnet affect each other, so that the first annular magnet and the second annular magnet are biased toward and tend to lock to one another, and to thereby move in the same direction as one another;
- d. a second sleeve (72) encasing the second annular magnet (44), the second annular magnet being longitudinally and reciprocally slideable between the first sleeve (68) and the second sleeve in substantially fluid-tight relation to the first sleeve and the second sleeve, and the second sleeve (72) defining an annular space (86) radially outwardly of the first sleeve (68) for longitudinal travel therein of the second annular magnet (44), the annular space (86) being in fluid communication with a hydraulic pump for actuating the second annular magnet (44); and
- e. an one-way valve (70) connected to the first annular magnet (54) and disposed transversely in relation to the longitudinal axis of the first annular magnet (54),

the one-way valve being movable with the first magnet, and closed when moving away from the origin of the valve annulus when the device is in normal use position, to thereby cause blood of the patient to move out of a diseased ventricle and toward the great vessels associated with that diseased ventricle as the first annular magnet (54) moves in a direction toward the great vessels of the diseased ventricle due to magnetic flux of the second annular magnet, the one-way valve further being adapted to be open when moving in a direction away from the great vessels of the diseased ventricle, to thereby permit blood of the patient to flow through the one-way valve into the space defined by the first sleeve (68) when the second annular magnet moves away from the great vessels of the diseased ventricle;

and further wherein the hydraulic pumping assembly comprises:

a. a hydraulic pump (42) having:

at least one electromagnetic coil (46, 48, 50) encapsulated so as to be fluid-tight, and defining a pumping chamber for retaining hydraulic fluid (52) therein, the pumping chamber having first and second opposed ends;

a first end cap (56) and a second end cap (57) connected at opposed first and second ends of the pumping chamber, respectively, the first end cap and the second end cap each having an aperture in fluid communication with a hydraulic fluid line,

a substantially solid high ferromagnetic-constant magnet (40) disposed longitudinally, slideably and reciprocally within the pumping chamber to act as a piston for driving hydraulic fluid

within the pumping chamber in response to signals from a  
batter/controller assembly;

b. a fluid line (59, 60) having a first end and a second end, the first end of the fluid line being connected to and in fluid communication with an aperture in the first end cap and the second end of the fluid line being connected to and in fluid communication with an aperture in the second end cap, and the VAD being in fluid communication with the hydraulic pumping assembly at a point on the fluid line between the first end and the second end of the fluid line;

c. a check valve (84) operatively connected in the fluid line between the connection of the first end of the fluid line and the second end of the fluid line to the first and second end caps respectively, and the fluid line being in fluid communication with the VAD, after the point of connection of the check valve and before the connection of the second end of the fluid valve and the second end cap of the pump cylinder; and

d. a battery/controller assembly (65) operatively connected to the check valve and to the at least one electromagnetic coil to provide electric power and control signals to the pump, the battery controller assembly in electrical communication with the native heart of the patient using the system, to thereby receive electronic information, including at least portions of ECG signals, blood pressure signals and/or blood volume signals, from the native heart.

Claim 54. (original): The system of Claim 53, wherein the entire device (58, 74) is of sufficiently small size and weight for placement in normal operative position between the

valve annulus and the great vessels of the diseased ventricle of a patient using the device, to assist or replace the function of at least a portion of the diseased native heart.

Claim 55. (original): The system of Claim 53, wherein the battery controller assembly and the hydraulic pump are of sufficiently small size and weight to be entirely contained within the abdominal cavity of the patient using the system and the VAD is of sufficiently small size and weight to be entirely contained within the chest cavity of the patient using the system, and the complete system, including all wires and hydraulic fluid lines, is entirely contained within the body of the patient, so that there is no part of the system extending exterior of the skin of a patient using the system when the system is in normal use position in the patient.

Claim 56. (original): A BI-VAD assembly to assist the function of both the right and left cardiac ventricles simultaneously, the BI-VAD assembly comprising:

a. a L-VAD disposed between the aortic valve and the aortic arch, to thereby permit blood to move from the left ventricle of the native heart through the aortic valve and into the L-VAD of a patient using the system, the L-VAD pumping blood into the aortic arch; and

b. a R-VAD disposed between the pulmonary valve and the bifurcation of the pulmonary trunk in normal use position in a patient using the BI-VAD, to thereby permit blood to move from the right ventricle of the patient through the pulmonary valve and into the R-VAD as the R-VAD pumps blood into the bifurcation of the pulmonary arteries of the patient.

Claim 57. (original): A BI-VAD assembly (77) to assist the function of both the right and left cardiac ventricles simultaneously, the BI-VAD assembly comprising:

- a. a L-VAD and a R-VAD;
- b. the L-VAD being sized and shaped for positioning between the aortic valve and the aortic arch of the patient using the device;  
the L-VAD comprising:
  - a. a first magnet having an open center and formed of high ferromagnetic-constant material;
  - b. a first vessel surrounding the first magnet and defining a space in fluid communication with the aortic arch of the patient using the device, the first magnet being movable within the first vessel in substantially fluid-tight relation thereto;
  - c. a second magnet formed of high ferromagnetic-constant material and being in magnetic communication with the first magnet, so that the respective magnetic fluxes of the first magnet and the second magnet affect each other, so that the first magnet and the second magnet are biased toward and tend to lock to one another, to thereby move in the same direction as one another;
  - d. a second vessel encasing the second magnet and defining a space, the second magnet being movable within the space in substantially fluid-tight relation to the second vessel, the space defined by the second vessel being in fluid communication with a hydraulic pump for actuating the second magnet; and

- e. an one-way valve connected to the corresponding first magnet of the L-VAD , the one-way valve being movable with the first magnet of the L-VAD and closed when moving in a direction toward the aortic arch when the device is in normal use position in a patient using the device, to thereby cause blood of the patient to push through the aortic arch as the first magnet moves toward the aortic arch of the patient when the second magnet is actuated to move toward the aortic arch, the one-way valve in the L-VAD further being open when moving away from the aortic arch, to thereby permit blood of the patient to flow through the one-way valve of the L-VAD into the space defined by the first vessel when the second magnet of the L-VAD is moved away from the aortic arch; and
- c. the R-VAD being sized and shaped for positioning between the pulmonary valve and the bifurcation of the pulmonary trunk of the patient using the device and connected to the L-VAD;

the R-VAD comprising:

- a. a first magnet having an open center and formed of high ferromagnetic-constant material;
- b. a first vessel surrounding the first magnet and defining a space in fluid communication with the bifurcation of the pulmonary arteries of the patient using the device, the first magnet being movable within the first vessel in substantially fluid-tight relation thereto;
- c. a second magnet formed of high ferromagnetic-constant material and being in magnetic communication with the first magnet, so that the first



magnet and the second magnet are biased toward and tend to lock to one another, to thereby move in the same direction as one another;

d. a second vessel encasing the second magnet and defining a space, the second magnet being movable within the space in substantially fluid-tight relation to the second vessel, the space defined by the second vessel being in fluid communication with a hydraulic pump for actuating the second magnet; and

e. an one-way valve being movable with the first magnet of the R-VAD and closed when moving toward the bifurcation of the pulmonary arteries when the R-VAD is in normal use position in a patient using the assembly, to thereby cause blood of the patient to push through the bifurcation of the pulmonary arteries as the first magnet of the R-VAD moves toward such bifurcation when the second magnet of the R-VAD is actuated to move toward the bifurcation, the one-way valve of the R-VAD further being open when moving away from the bifurcation of the pulmonary arteries, to thereby permit blood of the patient to flow through the one-way valve of the R-VAD into the space defined by the first vessel when the second magnet of the R-VAD is moved away from the bifurcation of the pulmonary arteries.

Claim 58. (original): A system for assisting cardiac ventricular function simultaneously in both diseased ventricles of the native heart of a patient using the system, the system comprising at least one hydraulic pumping assembly and two cardiac ventricular assist devices in fluid communication with the at least one hydraulic pumping assembly, wherein the ventricular assist devices comprise:

a. a L-VAD disposed between the aortic valve and the aortic arch of the patient, to thereby permit blood to move from the left ventricle of the native heart through the aortic valve and into the L-VAD in a patient using the system, the L-VAD pumping blood into the aortic arch; and

b. a R-VAD disposed between the pulmonary valve and bifurcation of the pulmonary trunk in normal use position in a patient using the BI-VAD, to thereby permit blood to move from the right ventricle of the patient through the pulmonary valve and into the R-VAD as the R-VAD pumps blood into the bifurcation of the pulmonary arteries of the patient; and

wherein the at least one hydraulic pumping assembly comprises:

a. a hydraulic pump having:

an encapsulated pumping chamber for retaining hydraulic fluid therein, the pumping chamber having opposed first and second ends;

at least one electromagnetic coil surrounding the pumping chamber; and

a substantially solid high ferromagnetic-constant magnet disposed longitudinally, slideably and reciprocally within the pumping chamber to act as a piston for driving hydraulic fluid within the pumping chamber in response to signals from a battery/controller assembly;

b. a fluid line having a first end and a second end, the first end of the fluid line being connected to and in fluid communication with an the first end of the pumping chamber and the second end of the fluid line being connected to and in fluid communication with the second end of the pumping chamber, the L-VAD

and the R-VAD being in fluid communication with the fluid line at a point on the fluid line after the point of connection of the check valve and before the connection of the second end of the fluid line and the second end pump chamber; and

c. a battery/controller assembly operatively connected to the check valve and to the at least one electromagnetic coil to provide electric power and control signals to the pump, the battery controller assembly in electrical communication with the native heart of the patient using the system, to thereby receive signals corresponding to physiological parameters from the native heart.

Claim 59. (original): The system of claim 58, wherein the at least one hydraulic pumping assembly is two hydraulic pumping assemblies and the L-VAD and the R-VAD are each in fluid communication with a separate one of the two hydraulic pumping assemblies.

Claim 60. (original): A system for completely replacing cardiac ventricular function in a diseased native heart, the system comprising:

- a. a hydraulic pumping system; and
- b. a BI-VAD assembly having a L-VAD and a R-VAD, the L-VAD and the R-VAD having sufficient stroke volumes to supply the total cardiac blood flow output for the diseased native heart of a patient using the system, the L-VAD being disposed to at least partly replace the diseased left ventricle of the native heart of the patient and the R-VAD being disposed in normal use position to at least partly replace the diseased right ventricle of the native heart of the patient, with the inlet of the R-VAD being grafted to

an artificial heart valve and the outlet of the R-VAD being grafted into the pulmonary trunk of the patient; wherein the L-VAD comprises:

- a. a first magnet having an open center and formed of high ferromagnetic-constant material;
- b. a first vessel surrounding the first magnet and defining a space in fluid communication with the aortic arch of the patient using the device, the first magnet being movable within the first vessel in substantially fluid-tight relation thereto;
- c. a second magnet formed of high ferromagnetic-constant material and being in magnetic communication with the first magnet, so that the first magnet and the second magnet are biased toward and tend to lock to one another, to thereby move in the same direction as one another;
- d. a second vessel encasing the second magnet and defining a space, the second magnet being movable within the space in substantially fluid-tight relation to the second vessel, the space defined by the second vessel being in fluid communication with a hydraulic pump for actuating the second magnet; and
- e. an one-way valve connected to the corresponding first magnet of the L-VAD, the one-way valve being movable with the first magnet of the L-VAD and closed when moving in a direction toward the aortic arch when the device is in normal use position in a patient using the device, to thereby cause blood of the patient to push through the aortic arch as the first magnet moves toward the aortic arch of the patient when the second magnet is actuated to move toward the aortic arch, the one-way valve in the L-VAD further being open when

moving away from the aortic arch, to thereby permit blood of the patient to flow through the one-way valve of the L-VAD into the space defined by the first vessel when the second magnet of the L-VAD is moved away from the aortic arch; and wherein the R-VAD comprises:

- a. a first magnet having an open center and formed of high ferromagnetic-constant material;
- b. a first vessel surrounding the first magnet and defining a space in fluid communication with the bifurcation of the pulmonary arteries of the patient using the device, the first magnet being movable within the first vessel in substantially fluid-tight relation thereto;
- c. a second magnet formed of high ferromagnetic-constant material and being in magnetic communication with the first magnet, so that the respective magnetic fluxes of the first magnet and the second magnet affect each other, so that the first magnet and the second magnet are biased toward and tend to lock to one another, to thereby move in the same direction as one another;
- d. a second vessel encasing the second magnet and defining a space, the second magnet being movable within the space in substantially fluid-tight relation to the second vessel, the space defined by the second vessel being in fluid communication with a hydraulic pump for actuating the second magnet; and
- e. an one-way valve being movable with the first magnet of the R-VAD and closed when moving toward the bifurcation of the

pulmonary arteries when the R-VAD is in normal use position in a patient using the assembly, to thereby cause blood of the patient to push through the bifurcation of the pulmonary arteries as the first magnet of the R-VAD moves toward such bifurcation when the second magnet of the R-VAD is actuated to move toward the bifurcation, the one-way valve of the R-VAD further being open when moving away from the bifurcation of the pulmonary arteries, to thereby permit blood of the patient to flow through the one-way valve of the R-VAD into the space defined by the first vessel when the second magnet of the R-VAD is moved away from the bifurcation of the pulmonary arteries;

wherein the at least one hydraulic pumping assembly comprises:

a. a hydraulic pump having:

an encapsulated pumping chamber for retaining hydraulic fluid therein, the pumping chamber having opposed first and second ends;

at least one electromagnetic coil surrounding the pumping chamber; and

a substantially solid high ferromagnetic-constant magnet disposed longitudinally, slideably and reciprocally within the pumping chamber to act as a piston for driving hydraulic fluid within the pumping chamber in response to signals from a battery/controller assembly;

b. a fluid line having a first end and a second end, the first end of the fluid line being connected to and in fluid communication with an the first end of the pumping chamber and the second end of the fluid line being connected to and in fluid communication with the second end of the pumping chamber, the L-VAD and the R-VAD being in fluid communication with the fluid line at a point on the fluid line after the point of connection of the check valve and before the connection of the second end of the fluid line and the second end pump chamber; and

c. a battery/controller assembly operatively connected to the check valve and to the at least one electromagnetic coil to provide electric power and control signals to the pump, the battery controller assembly in electrical communication with the native heart of the patient using the system, to thereby receive signals corresponding to physiological parameters from the native heart.

Claim 61. (original): A system for assisting cardiac ventricular function, the system comprising:

a. a ventricular assist device (VAD) having:  
an open-centered magnet,  
at least one encapsulated electromagnetic coil in magnetic communication with the open-centered magnet; to thereby drive the magnet; and

a one-way valve connected to the open-centered magnet, the one-way valve being movable with the magnet, and adapted to cause movement of blood from the diseased ventricle to and into the great vessel associated with the diseased ventricle;

b. a battery/controller assembly operatively connected to the at least one electro-magnetic coil for energizing same and connected to the sino-atrial node of the patient when the system is in normal operative position in the patient to thereby provide signals to the VAD from the sino-atrial node to activate the at least one electromagnetic coil to optimally complement the function of the diseased ventricle of the patient's native heart